

## Actions Taken by FDA Center for Veterinary Medicine

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The following corrections or additions to the January 15, 1997 list were made in December, 1997

### New Approvals

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#### **ANADA Number: 200-189**

Pioneer Product: 111-636  
Trade Name : Lincomycin Soluble  
Ingredients: Lincomycin hydrochloride  
Sponsor: I.D. Russell Co. Laboratories  
Approval Date: 11/07/97  
Status: Over-the-counter  
Route: Oral  
Species: Porcine, avian (broiler chickens)  
Drug Form: Powder  
Concentration: 16 g/package  
Indications: For the treatment of dysentery (bloody scours) in swine and for the control of necrotic enteritis in broiler chickens caused by *Clostridium perfringens* susceptible to lincomycin  
Tolerance: 21CFR 556.360: 0.1 ppm for negligible residues in edible tissues of swine.  
Tolerance in chickens not required.  
Withdrawal: Swine: 6 days; chickens: zero days

*21CFR 520.1263c*

#### **ANADA Number: 200-213**

Pioneer Product: 045-348  
Trade Names : DECCOX          ALBAC  
Ingredients: Decoquinat, bacitracin zinc  
Sponsor: Alpharma, Inc.  
Approval Date: 09/22/97  
Status: Over-the-counter  
Route: Oral  
Species: Avian (broiler chickens)  
Drug Form: Type A medicated articles to make type C medicated feed  
Concentration: Decoquinat: 27.2 g/lb; bacitracin zinc: 50 g/lb  
Indications: As an aid in the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, and for increased rate of weight gain and improved feed efficiency.  
Tolerance: 21CFR 556.70: Bacitracin zinc: 0.5 ppm negligible residue in uncooked edible tissues of chickens.  
21CFR 556.170: Decoquinat: 2 ppm in uncooked edible tissues other than skeletal muscle, and 1 ppm in skeletal muscle of chickens.  
Withdrawal: Not required.

*21CFR 558.195*

## Actions Taken by FDA Center for Veterinary Medicine

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### ANADA Number: 200-209

Pioneer Product: 200-143  
Trade Names : SACOX                      ALBAC                      3-NITRO  
Ingredients: Salinomycin, bacitracin zinc, roxarsone  
Sponsor: Alpharma, Inc.  
Approval Date: 12/23/97  
Status: Over-the-counter  
Route: Oral  
Species: Avian (broiler chickens)  
Drug Form: Type A medicated articles to make type C medicated feed  
Concentration: Salinomycin: 30 g/lb; bacitracin zinc: 50 g/lb; roxarsone: 45.4 g/lb  
Indications: For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, and for increased rate of weight gain and improved feed efficiency.  
  
Tolerance: A tolerance for salinomycin is not required.  
21CFR 556.70: Bacitracin zinc: 0.5 ppm negligible residue in uncooked edible tissues of chickens.  
21CFR 556.60: Arsenic residues (from roxarsone): 0.5 ppm in uncooked edible muscle and 2 ppm in uncooked edible by-products of chickens.  
  
Withdrawal: 5 days.

This ANADA provides for the combined use of three approved type A medicated articles in type C medicated feeds, rather than a premix incorporating these three compounds.

21CFR 558.550

### ANADA Number: 200-215

Pioneer Product: 139-190  
Trade Names : BIO-COX                      ALBAC                      3-NITRO  
Ingredients: Salinomycin, bacitracin zinc, roxarsone  
Sponsor: Alpharma, Inc.  
Approval Date: 12/23/97  
Status: Over-the-counter  
Route: Oral  
Species: Avian (broiler chickens)  
Drug Form: Type A medicated articles to make type C medicated feed  
Concentration: Salinomycin: 30 g/lb; bacitracin zinc: 50 g/lb; roxarsone: 45.4 g/lb  
Indications: For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, and for increased rate of weight gain and improved feed efficiency.  
  
Tolerance: A tolerance for salinomycin is not required.  
21CFR 556.70: Bacitracin zinc: 0.5 ppm negligible residue in uncooked edible tissues of chickens.  
21CFR 556.60: Arsenic residues (from roxarsone): 0.5 ppm in uncooked edible muscle and 2 ppm in uncooked edible by-products of chickens.  
  
Withdrawal: 5 days.

This ANADA provides for the combined use of three approved type A medicated articles in type C medicated feeds, rather than a premix incorporating these three compounds.

21CFR 558.550

## Actions Taken by FDA Center for Veterinary Medicine

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### ANADA Number: 200-212

Pioneer Product: 096-933  
Trade Names : ROBENZ                      ALBAC  
Ingredients: Robenidine hydrochloride, bacitracin zinc  
Sponsor: Alpharma, Inc.  
Approval Date: 12/23/97  
Status: Over-the-counter  
Route: Oral  
Species: Avian (broiler chickens)  
Drug Form: Type A medicated articles to make type C medicated feed  
Concentration: Robenidine: 30 g/lb; bacitracin zinc: 50 g/lb  
Indications: As an aid in the prevention of coccidiosis caused by *Eimeria mivati*, *E. brunetti*, *E. tenella*, *E. acervulina*, *E. maxima*, and *E. necatrix*; and, in the presence of 4 to 30 g/ton bacitracin zinc, for increased rate of weight gain; and, in the presence of 27 to 50 g/ton bacitracin zinc, for improved feed efficiency.  
Tolerance: A tolerance for salinomycin is not required.  
21CFR 556.70: Bacitracin zinc: 0.5 ppm negligible residue in uncooked edible tissues of chickens.  
21CFR 556.580: Robenidine hydrochloride: 0.2 ppm in skin and fat, and 0.1 ppm (negligible residues) in edible tissues other than skin and fat of chickens.  
Withdrawal: 5 days.

This ANADA provides for the combined use of two approved type A medicated articles in type C medicated feeds, rather than a premix incorporating both of these compounds.

21CFR 558.515

### ANADA Number: 200-217

Pioneer Product: 039-284  
Trade Names : AMPROL HI-E                      ALBAC                      3-NITRO  
Ingredients: Amprolium, ethopabate, bacitracin zinc, roxarsone  
Sponsor: Alpharma, Inc.  
Approval Date: 12/23/97  
Status: Over-the-counter  
Route: Oral  
Species: Avian (broiler chickens)  
Drug Form: Type A medicated articles to make type C medicated feed  
Concentration: Amprolium: 113.5 g/lb; ethopabate: 36.3 g/lb; bacitracin zinc: 50 g/lb; roxarsone: 45.4 g/lb  
Indications: As an aid in the prevention of coccidiosis where severe exposure to coccidiosis from *Eimeria acervulina*, *E. maxima*, and *E. brunetti* is likely to occur, and for increased rate of weight gain in broiler chickens raised in floor pens.  
Tolerance: 21CFR 556.50: Amprolium: 1 ppm in the uncooked liver and kidney, and 0.5 ppm in uncooked muscle.  
21CFR 556.260: Ethopabate: 1.5 ppm of m-phenetidine (metabolite) in the uncooked liver and kidney, and 0.5 ppm in uncooked muscle.  
21CFR 556.70: Bacitracin zinc: 0.5 ppm negligible residue in uncooked edible tissues of chickens.  
21CFR 556.60: Arsenic residues (from roxarsone): 0.5 ppm in uncooked edible muscle and 2 ppm in uncooked edible by-products of chickens.  
Withdrawal: 5 days.

This ANADA provides for the combined use of three approved type A medicated articles in type C medicated feeds, rather than a premix incorporating all three of these compounds.

21CFR 558.58

## **Actions Taken by FDA Center for Veterinary Medicine**

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## Actions Taken by FDA Center for Veterinary Medicine

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### ANADA Number: 200-206

Pioneer Product: 091-326  
Trade Names : DECCOX            ALBAC            3-NITRO  
Ingredients: Decoquinate, bacitracin zinc, roxarsone  
Sponsor: Alpharma, Inc.  
Approval Date: 12/24/97  
Status: Over-the-counter  
Route: Oral  
Species: Avian (broiler chickens)  
Drug Form: Type A medicated articles to make type C medicated feed  
Concentration: Decoquinate: 27.2 g/lb; bacitracin zinc: 50 g/lb; roxarsone: 45.4 g/lb  
Indications: For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. mivati*, *E. maxima*, and *E. brunetti*, and for increased rate of weight gain and improved feed efficiency.  
Tolerance: 21CFR 556.170: Decoquinate: 2 ppm in tissues other than skeletal muscle and 1 ppm in skeletal muscle  
21CFR 556.70: Bacitracin zinc: 0.5 ppm negligible residue in uncooked edible tissues of chickens.  
21CFR 556.60: Arsenic residues (from roxarsone): 0.5 ppm in uncooked edible muscle and 2 ppm in uncooked edible by-products of chickens.  
Withdrawal: 5 days.

This ANADA provides for the combined use of three approved type A medicated articles in type C medicated feeds, rather than a premix incorporating all three of these compounds.

21CFR 558.195

### ANADA Number: 200-140

Pioneer Product: 039-077  
Trade Name : Aureozol  
Ingredients: Chlortetracycline, sulfathiazole, penicillin procaine  
Sponsor: Hoffmann-La Roche, Inc.  
Approval Date: 12/30/97  
Status: Over-the-counter  
Route: Oral  
Species: Porcine  
Drug Form: Type A medicated articles to make type C medicated feed  
Concentration: Chlortetracycline calcium complex equivalent to chlortetracycline HCl: 20 g/lb; sulfathiazole: 20 g/lb; penicillin (from procaine penicillin): 10 g/lb.  
Indications: Pre-starter and starter feeds: for reduction of the incidence of cervical abscesses; treatment of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis* and vibronic dysentery); maintenance of weight gains in the presence of atrophic rhinitis; increased rate of weight gain and improved feed efficiency from 10 lbs of body weight to 6 weeks post-weaning. For swine raised in confinement (dry lot) or on limited pasture.  
Grower and finisher feeds: for reduction of the incidence of cervical abscesses; treatment of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis* and vibronic dysentery); maintenance of weight gains in the presence of atrophic rhinitis; increased rate of weight gain from 6 to 16 weeks post-weaning. For swine raised in confinement (dry lot) or on limited pasture.  
Tolerance: 21CFR 556.690: Sulfathiazole: 0.1 ppm (negligible residues) in edible tissues of swine.  
21CFR 556.510: Penicillin: Zero.  
21CFR 556.150: Chlortetracycline: 12 ppm in fat and kidney, 6 ppm in liver, and 2 ppm in muscle.  
Withdrawal: 7 days.

21CFR 558.155

## Actions Taken by FDA Center for Veterinary Medicine

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### NADA Number: 141-066

Trade Names : AVIAX™ 3-NITRO  
Ingredients: Semduramicin, roxarsone  
Sponsor: Pfizer, Inc.  
Approval Date: 12/23/97  
Status: Over-the-counter  
Route: Oral  
Species: Avian (broiler chickens)  
Drug Form: Type A medicated articles to make type C medicated feeds.  
Concentration: Semduramicin: 22.7 g/lb; roxarsone: 45.4 g/lb  
Indications: For the prevention of coccidiosis in broiler chickens caused by *Eimeria acervulina*, *E. brunetti*, *E. maxima/mitis*, and *E. tenella*, including some field strains of *E. tenella* that are more susceptible to semduramicin combined with roxarsone than semduramicin alone.  
Tolerance: A tolerance for semduramicin residues is not required.  
21CFR 556.60: Arsenic residues (from roxarsone): 0.5 ppm in uncooked edible muscle and 2 ppm in uncooked edible by-products of chickens.  
Withdrawal: 5 days.  
Patent Number: 4804680 Expiration date: 07/21/2007  
4912130 07/21/2007  
4992466 02/12/2008  
5385735 01/31/2012  
Exclusivity: 3 years

21CFR 558.555

### NADA Number: 141-095

Trade Name : Dectomax pour-on solution  
Ingredients: Doramectin  
Sponsor: Pfizer, Inc.  
Approval Date: 09/16/97  
Status: Over-the-counter  
Route: Topical  
Species: Bovine (beef cattle and non-lactating dairy cattle)  
Drug Form: Liquid (solution)  
Concentration: 5 mg/mL  
Indications: For the treatment and control of the following species of gastrointestinal roundworms, lungworms, eyeworms, grubs, biting and sucking lice, and mange mites in cattle.  
Gastrointestinal roundworms: *Ostertagia ostertagi* (adults and L4, including inhibited larvae), *Ostertagia lyrata* (adults), *Haemonchus placei* (adults and L4), *Trichostrongylus axei* (adults), *Trichostrongylus colubriformis* (adults and L4), *Cooperia oncophora* (adults and L4), *Cooperia pectinata* (adults), *Cooperia punctata* (adults and L4), *Cooperia surnabada* (adults), *Bunostomum phlebotomum* (adults), *Oesophagostomum radiatum* (adults and L4), *Trichuris* spp. (adults).  
Lungworms: *Dictyocaulus viviparus* (adults and L4).  
Eyeworms: *Thelazia gulosa* (adults), *Thelazia skrjabini* (adults).  
Grubs: *Hypoderma bovis*, *Hypoderma lineatum*.  
Lice: Biting lice: *Damalinia bovis*; sucking lice: *Haematopinus eurysternus*, *Linognathus vituli*, *Solenopotes capillatus*.  
Mange mites: *Chorioptes bovis*, *Sarcoptes scabiei*.

The product has proved to effectively control infections and to protect cattle from reinfection with *Cooperia oncophora* and *Dictyocaulus viviparus* for 21 days, and *Ostertagia ostertagi*, *Cooperia punctata*, and *Oesophagostomum radiatum* for 28 days after treatment.  
Tolerance: 21CFR 556.225: 0.1 ppm in liver.

## Actions Taken by FDA Center for Veterinary Medicine

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**NADA Number: 141-095, con't**

Withdrawal: 45 days.  
Patent Number: 5,089,480      Expiration date: 02/18/2009  
Exclusivity: 3 years

*21CFR 524.770*

**NADA Number: 141-071**

Trade Name : IMIZOL  
Ingredients: Imidocarb dipropionate  
Sponsor: Schering-Plough Animal Health Corp.  
Approval Date: 11/07/97  
Status: Prescription only  
Route: Intramuscular, subcutaneous  
Species: Canine  
Drug Form: Liquid (solution)  
Concentration: 120 mg/mL  
Indications: For the treatment of dogs with clinical signs of babesiosis and/or demonstrated *Babesia* organisms in the blood.  
Exclusivity: 3 years.

*21CFR 522.1156*

### Change of Sponsor

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The following NADAs were transferred from Rhone-Poulenc, Inc. to Alparma, Inc.:

039-417  
040-435  
045-348  
045-444  
047-262  
091-326  
092-953

## Actions Taken by FDA Center for Veterinary Medicine

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### Suitability Petition Actions

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Number.: 97P-0473 CP1  
Sponsor: Macleod Pharmaceuticals, Inc.  
Petition: Request permission to file an ANADA for a generic new animal drug, Unibute Paste (phenylbutazone paste) which differs from the pioneer product, Butazolidin Paste, Mallinkrodt Veterinary, Inc., NADA 116-087 by the following characteristics:  
Unibute Paste: 20 g of phenylbutazone per 60 g of paste. Butazolidin Paste (pioneer): 12 g of phenylbutazone per 60 g of paste. The dosage (1-2 g of phenylbutazone/500 lbs body weight) is the same in both products.  
Action: Filed on 11/18/97.

Number.: 97P-0474 CP1  
Sponsor: Macleod Pharmaceuticals, Inc.  
Petition: Request permission to file an ANADA for a generic new animal drug, Uniprim Paste (trimethoprim and sulfadiazine) which differs from the pioneer product, Tribriksen 400 Oral Paste, Mallinkrodt Veterinary, Inc., NADA 131-918 by the following characteristics:  
Uniprim Paste: 56 mg of trimethoprim and 278 mg sulfadiazine per gram. Tribriksen Oral Paste (pioneer): 67 mg of trimethoprim and 333 mg sulfadiazine per gram. The dosage (30 mg/kg body weight) is the same in both products.  
Action: Filed on 11/18/97.